

Remarks

Correction of Claim Identifiers

The Examiner has requested that errors in the claim identifiers used in the Preliminary Amendment filed with the RCE in response to the Advisory Action dated March 26, 2004, be corrected. The status identifier corrections are reflected in the above claim amendments.

Rejection Under 35 USC §112, First Paragraph

Claims 1-23 are rejected under 35 USC §112, first paragraph, as the specification is allegedly enabling only for methods of treating cancer. In this response the claims have been amended to delete reference to methods of preventing cancer, and it is submitted that this rejection has been overcome. Withdrawal thereof is respectfully requested.

Rejection Under 35 USC §102(b)

The previous rejection of claims 1, 4, 5 and 13-18 under 35 USC §102(b) as anticipated by Webb et al in the Office Action dated July 26, 2004, has been withdrawn in view the Examiner's misinterpretation of the phrase "consisting essentially of" in the rejected claims, as argued by Applicants in the response dated October 22, 2004. However, that rejection has now been replaced by a rejection of claims 1-5 and 13-18 under 35 USC §102(b) as anticipated by Webb et al.

The present rejection is a reiteration, without any substantial change in logic or reasoning, of the rejection first put forth by the Examiner in the Office Action dated December 15, 2003, in which Examiner alleged that Webb's 14-day course of treatment

encompassed Applicants' shorter cycles of 2-3 days, i.e., that the 14-day course of treatment taught by Webb could be interpreted as two cycles of 7 days each. In response to the subsequent Advisory Action of March 26, 2004, Applicants on May 10, 2004, filed an RCE with a Preliminary Amendment in which all claims were limited to treatment cycles "consisting of" 2-13 days. In the Preliminary Amendment Applicants argued that:

"Further, on page 1138, second paragraph in describing the therapy in more detail, Webb states: '**One 2-week course of treatment was given.** Patients were followed up for 4 weeks after the end of treatment. If there was evidence of tumor response, **a second course was considered.**' Thus, Webb clearly does not teach two cycles of therapy where each cycle of therapy is 7 days, let alone a cycle of therapy for 2-13 days. At the most Webb suggests is [sic] a cycle of therapy for 14 days, possibly followed by a second cycle to be administered 4 weeks after the end of the first cycle.

It appears that the Examiner is trying to argue that each day of the treatment in Webb is a cycle of therapy. It is clear from Webb et al. that the term 'course' of therapy does not mean 'days.' The quoted passage provided above indicates that the cycle (or course) was for 2 weeks. Webb contemplated providing another cycle/course of treatment after a 4 week rest. It is clear that Webb does not teach or suggest that the cycle of [sic] course of therapy was for 7 days. To arrive at the Examiner's conclusion that Webb teaches two cycles of 7 day treatments, one must ignore the explicit teachings and language of Webb." (emphasis added - pg. 7, ln. 23-pg. 8, ln. 6 of the Preliminary Amendment dated May 10, 2004)

In response to Applicants' arguments in the Preliminary Amendment, the Examiner stated in the Office Action dated July 26, 2004:

"Applicant's arguments have been fully considered **and are found persuasive.** **The Examiner agrees that Webb teaches treating a human with one cycle of therapy for 14 days.** In view of this, this rejection has been withdrawn against claims 2 and 3. However, this rejection is maintained against claims 1, 4, 5 and 13-18 for the following reasons: As Applicants has eluded, Webb teaches treating a human with one cycle of therapy for 14 days. The instant claims are drawn to treating a human with one or more cycles of therapy, each cycle of therapy consisting of 2-13 days." (emphasis added - pg. 3, last para. of the July 26, 2004, Office Action)

The Examiner then went on to draw Applicants' attention to MPEP §2111.03, citing the meaning of the transitional phrase "consisting essentially of," which was not the transitional phrase used in claims 1, 4, 5 and 13-18. Applicants' response dated October 22, 2004, pointed out that the "consisting of" transitional phrase used in the rejected claims is equivalent in its scope to the "consists of" transitional phrase used in claims 2 and 3 (for which the rejection had been withdrawn) and similarly excludes any additional steps or components from the length of the treatment cycle.

In the present Office Action, having completely accepted Applicants' arguments with respect to the phrase "consisting of" or "consists of" for all claims in question and withdrawing the rejection (pg. 4, first paragraph of "Claim Rejections – 35 USC §102"), the Examiner repeats the rejection first presented in the December 15, 2003, Office Action, then reconsidered and withdrawn in the July 26, 2004, Office Action in view of Applicants' arguments. The July 26, 2004, Office Action introduced the Examiner's misinterpretation of "consisting of," and that rejection, too, has now been withdrawn. Having admitted in the July 26, 2004, Office Action that Webb does indeed teach a 14-day cycle of therapy, the Examiner without providing any reason now returns to the previous position that it does not. The present rejection does not present any fact or interpretation of the Webb et al reference that Applicant has not already argued and overcome. The rejection of claims 1-5 and 13-18 as anticipated by Webb et al. must therefore be withdrawn as before.

Rejection Under 35 USC §103

The rejection of claims 1-23 as unpatentable over Webb et al. in view of Bennett et al. has been withdrawn in view of the Examiner's previous misinterpretation of the transitional phrase "consisting of" in the rejected claims. However, as was done in the rejection under 35 USC §102(b) discussed above, the Examiner now applies the same references in a §103 rejection reverting to a previous position that Webb et al. teaches treatment cycles of less than 14 days – a position which was reconsidered and withdrawn in the prior Office Action of July 26, 2004. The Examiner points out in the Response to Arguments that the references cannot be argued individually and the primary reference Webb et al.:

“....clearly teach successful administration of a bcl-2 antisense drug in 2 to 13 day cycles.” (pg. 12, lns. 16-17 of the present Office Action)

This statement clearly contradicts the Examiner's previous position on this same point, which was:

“Applicant's arguments have been fully considered and are found persuasive. ***The Examiner agrees that Webb teaches treating a human with one cycle of therapy for 14 days.***” (see discussion above)

The present rejection is based on the premise that Webb et al. teach treatment cycles of 2-13 days. That premise was reconsidered and the §102(b) rejection was withdrawn because the Examiner agreed that Webb et al. teaches only 14 day cycles. The primary reference in the present §103 rejection is therefore, by the Examiner's own admission, insufficient to teach the claimed treatment cycle. At most, Bennett adds only motivation to experiment with dosage and administration. Bennett does not, however, in any way

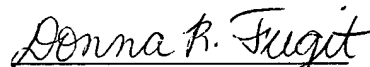
suggest the outcome of such experimentation if applied to Applicants' bcl-2 antisense drug. That is, Bennett does not teach or suggest the claimed invention, i.e., that (in clear contradiction of Webb et al.) a 2-13 day treatment cycle would be a successful treatment method for Applicants' bcl-2 antisense molecule. The combined references therefore neither teach or suggest a cycle of treatment consisting of 2-13 days and the rejection should be withdrawn.

Conclusion

Applicants respectfully submit that all rejections of and objections to the claims have been overcome and an action passing this case to issue is requested. If the Examiner would like to discuss any remaining issues in this application, she is invited to contact the undersigned at the number shown below.

Respectfully submitted,

BY:


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